



JH

PTO/SB/08a (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10593261
Filing Date	2007-07-11
First Named Inventor	Lars Michael Larsen
Art Unit	1614
Examiner Name	
Attorney Docket Number	LARSEN=5

**U.S.PATENTS**

Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	5552369		1996-09-03	FINDEISEN et al.	
	2	5624949		1997-04-29	William E. HEATH Jr. et al.	
	3	5674862		1997-10-07	William E. HEATH Jr. et al.	
	4	5698578		1997-12-16	William E. HEATH Jr. et al.	
	5	5710145		1998-01-20	Gaey Lowell ENGEL et al.	
	6	5824685		1998-10-20	Peter A. CAMPOCHIARO et al.	
	7	6015807		2000-01-18	Gaey Lowell ENGEL et al.	
	8	6114320		2000-09-05	Lloyd P. AIELLO et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10593261
Filing Date	2007-07-11
First Named Inventor	Lars Michael Larsen
Art Unit	1614
Examiner Name	
Attorney Docket Number	LARSEN=5

**U.S.PATENT APPLICATION PUBLICATIONS**

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20030032078	A1	2003-02-13	Gabriel H. TRAVIS	

If you wish to add additional U.S. Published Application citation information please click the Add button.

**FOREIGN PATENT DOCUMENTS**

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> i	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	2005107707	WO	A1	2005-11-17	Allergan, Inc.		<input type="checkbox"/>
	2	02080936	WO	A1	2002-10-17	Ortho McNeil Pharmaceutical, Inc.		<input type="checkbox"/>
	3	2005058304	WO	A1	2005-06-30	Cortical Pty Ltd.		<input type="checkbox"/>
	4	03104178	WO	A1	2003-12-18	Cortical Pty Ltd.		<input type="checkbox"/>
	5	02080935	WO	A1	2002-10-17	Ortho McNeil Pharmaceutical, Inc.		<input type="checkbox"/>
	6	03097052	WO	A2	2003-11-27	Celgene Corporation		<input type="checkbox"/>
	7	99058126	WO	A1	1999-11-18	The Endowment for Research in Human Biology, Inc.		<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		10593261
Filing Date		2007-07-11
First Named Inventor	Lars Michael Larsen	
Art Unit	1614	
Examiner Name		
Attorney Docket Number	LARSEN=5	

8	02072003	WO	A2	2002-09-19	Tomas HAGSTROM		<input type="checkbox"/>
9	02085400	WO	A1	2002-10-31	Supergen, Inc.		<input type="checkbox"/>
10	0198294	WO	A2	2001-12-27	Dupont Pharmaceuticals Company		<input type="checkbox"/>
11	03004058	WO	A1	2003-01-16	Santen Pharmaceutical Co.	Abstract	<input checked="" type="checkbox"/>
12	2005056010	WO	A1	2005-06-23	Allergan, Inc.		<input type="checkbox"/>
13	2005011741	WO	A2	2005-02-10	Allergan, Inc.		<input type="checkbox"/>
14	03082081	WO	A2	2003-10-09	Maxim Pharmaceuticals, Inc.		<input type="checkbox"/>
15	0522226	EP	A1	1993-01-13	Ciro COSTAGLIOLA		<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	PAUL A. SIEVING et al. "Inhibition of the visual cycle in vivo by 13-cis retinoic acid protects from light damage and provides a mechanism for night blindness in isotretinoin therapy", Proc. Nat. Acad. Sci. (USA), February 13, 2001, Vol. 98, No. 4, pages 1835-1840	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10593261
Filing Date	2007-07-11
First Named Inventor	Lars Michael Larsen
Art Unit	1614
Examiner Name	
Attorney Docket Number	LARSEN=5

2	ROXANA A. RADU et al., "Treatment with isotretinoin inhibits lipofuscin accumulation in a mouse model of recessive Stargard's macular degeneration", Proc. Nat. Acad. Sci. (USA), April 15, 2003, Vol. 100, No. 8, pages 4742-4747	<input type="checkbox"/>
3	JANET R. SPARROW, "Therapy for macular degeneration: Insights from acne", PNAS, April 15, 2003, Vol. 100, No. 8, pages 4353-4354	<input type="checkbox"/>
4	G. B. ARDEN, "The absence of diabetic retinopathy in patients with retinitis pigmentosa: implications for pathophysiology and possible", Br F Ophthalmol, 2001, Vol 85, pages 366-370	<input type="checkbox"/>
5	LERMAN, S., "Ocular side effects of accutane therapy", Lens and Eye Toxicity Research, 1992, Vol. 9(3-4), pages 429-38.	<input type="checkbox"/>
6	DEVIPRASAD R. GOLLAPALLI et al., "Specific inactivation of isomerohydrolase activity by 11-cis-retinoids", Science Direct, Biochimica et Biophysica Acta 1651 (2003) pages 93-101	<input type="checkbox"/>
7	DEVIPRASAD R. GOLLAPALLI et al., "All-trans-retinyl Esters Are the Substrates for Isomerization in the Vertebrate Visual Cycle", Biochemistry, April 25, 2003, Vol. 42 pages 5809-5818	<input type="checkbox"/>
8	DEVIPRASAD R. GOLLAPALLI et al., "RPE65 Operates in the Vertebrate Visual Cycle by Stereospecifically Binding All-trans-Retinyl Esters", Biochemistry, September 17, 2003, Vol. 42, pages 11824-11830	<input type="checkbox"/>
9	PAUL S. BERNSTEIN et al., "Mechanism of Action of Aromatic Amines That Short-Circuit the Visual Cycle", Biochemistry, 1986, Vol. 25, pages 3370-3377	<input type="checkbox"/>
10	N DRASDO et al., "Effect of darkness on inner retinal hypoxia in diabetes" The Lancet, Vol. 359, June 29, 2002, pages 2251-2253	<input type="checkbox"/>
11	ANETTE WINSTON et al., "Regulation of Isomerohydrolase Activity in the Visual Cycle", Biochemistry, February 3, 1998, Vol. 37, pages 2044-2050	<input type="checkbox"/>
12	G.B. ARDEN et al., "Does dark adaptation exacerbate diabetic retinopathy? Evidence and a linking hypothesis", Vision Research, Vol. 38, 1998, pages 1723-1729	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		10593261
Filing Date		2007-07-11
First Named Inventor	Lars Michael Larsen	
Art Unit	1614	
Examiner Name		
Attorney Docket Number	LARSEN=5	

13	ANNA WROBEL et al., "Antiangiogenic activity of agonist and antagonists of retinoid nuclear receptors", Przegląd Dermatologiczny, 1999, Vol. 86, No. 4, pages 339-346 (in Polish)	<input checked="" type="checkbox"/>
14	MICHAEL F. MARMOR, et al., "Albipunctate Retinopathy with cone Dysfunction and no Abnormality in the RDH5 or RLBPI Genes", Retina 2003 United States, Vol. 23, Vol. 4, pages 543-546	<input type="checkbox"/>
15	B. M. CALISSENDORFF, "Retinal changes degeneration or side effects caused by etretinate therapy Tigason" Klin. Mbl. Augenheilk., Vol. 194, 1989, pages 187-189 (in German)	<input checked="" type="checkbox"/>
16	TSUTOMU OIKAWA et al., "Three novel synthetic retinoids, Re 80, Am 580 and Am 80, all exhibit anti-angiogenic activity in vivo", Europ J. of Pharmac., Vol. 249, 1993, pages 113-116	<input type="checkbox"/>
17	SELIG HECHT et al., "Rod-Cone Dark Adaptation and Vitamin A", Science, New Series, Vol. 88, No. 2279, September 2, 1938, pages 219-221	<input type="checkbox"/>
18	JOHN E. DOWLING et al., "Vitamin a Deficiency and Night Blindness", Proc. Natl. Acad. Sci. USA Vol. 44, (1958) pages 648-661	<input type="checkbox"/>
19	RICHARD G. WELEBER et al., "Abnormal Retinal Function Associated with Isotretinoin Therapy for Acne", Arch Ophthalmol, Vol. 104, June 1986, pages 831-837	<input type="checkbox"/>
20	H. MACLEAN et al., "Abnormal night vision with isotretinoin therapy for acne", Clinical and Experimental Dermatol, Vol. 20, page 86, January 1995,	<input type="checkbox"/>
21	ROSALIE K. CROUCH et al., "Retinoids and the Visual Process", Photochem. Photobiol., Vol. 64, pages 613-621	<input type="checkbox"/>
22	F. T. FRAUNFELDER, et al., "Ocular Side Effects Possibly Associated with Isotretinoin Usage", Am. J. Ophthalmol, Vol. 132, 2001, pages 299-305	<input type="checkbox"/>
23	WING C. LAW et al., "The Molecular Basis of Retinoic Acid Induced Night Blindness" Biochem. Biophys. Res. Comm., Vol. 161, No. 2, pages 825-829	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10593261
Filing Date	2007-07-11
First Named Inventor	Lars Michael Larsen
Art Unit	1614
Examiner Name	
Attorney Docket Number	LARSEN=5

24	BELINDA M. WELSH et al., "Night blindness precipitated by isotretinoin in the setting of hypovitaminosis A", Australas J Dermatol, Vol. 40, 1999, pages 208-210	<input type="checkbox"/>
25	G. P. MOSS et al., "Nomenclature of Retinoids", Arch. Biochem., Biophys. Vol. 224, No. 2, July 15, 1983, pages 728-731	<input type="checkbox"/>
26	BRAHMA P. SANI et al., "Structural Characteristics of Synthetic Retinoids", Meth. In Enzymology, Vol. 189, 1990, pages 43-59	<input type="checkbox"/>
27	MICHAEL KLAUS, "Structure Characteristics of Natural and Synthetic Retinoids" Meth. In Enzymology, Vol. 189, (1990) pages 3-14	<input type="checkbox"/>
28	M. I. DAWSON et al., "Synthetic Retinoic Acid Analogs: Handling and Characterization", Meth. In Enzymology, Vol. 189, , 1990, pages 15-43	<input type="checkbox"/>
29	GREGORY M. ACLAND et al., "Gene therapy restores vision in a canine model of childhood blindness", Nature genetics, Vol. 28, May 2001, pages 92-95	<input type="checkbox"/>
30	T. MICHAEL REDMOND et al., "Rpe65 is necessary for production of 11-cis-vitamin A in the retinal visual cycle", Nature Genetics, Vol. 20, December 1998, pages 344-351	<input type="checkbox"/>
31	PAUL S. BERNSTEIN et al., "The Specific Inhibition of 11-cis-Retinyl Palmitate Formation in the Frog Eye by Diaminophenoxypentane, An inhibitor of Rhodopsin Regeneration", Vision Res., Vol. 25, No. 6, 1985, pages 741-748	<input type="checkbox"/>
32	BROWN, et al., "Visual toxicity of synthetic retinoids", British Journal of Ophthalmology, Vol. 73, pages 286-288, 1989.	<input type="checkbox"/>
33	CAFFERY, et al., "Ocular side effects of isotretinoin therapy", Journal of the American Optometric Association, Vol. 59, No. 3, pages 221-224, March 1988.	<input type="checkbox"/>
34	DENMAN, et al., Abnormal night vision and altered dark adaptometry in patients treated with isotretinoin for acne", Journal of the American Academy of Dermatology, Vol. 14, No. 4, pages 692-693, April 1986.	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10593261
Filing Date	2007-07-11
First Named Inventor	Lars Michael Larsen
Art Unit	1614
Examiner Name	
Attorney Docket Number	LARSEN=5

35	FEIST, et al., "Visual Side Effects of Isotretinoin Therapy", SOUTHERN MEDICAL JOURNAL, Vol. 80, No. 10, page 1332, October 1987.	<input type="checkbox"/>
36	FRAUNFELDER, et al., "Adverse Ocular Reactions Possibly Associated with Isotretinoin", American Journal of Ophthalmology, Vol. 100, pages 534-537, October 1985.	<input type="checkbox"/>
37	GROSS, et al., "Retinoids and the Eye", Dermatologic Clinics, Vol. 10, No. 3, pages 521-531, July 1992.	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.